

Dear Healthcare Providers,

As you may have heard, November 6, 2017, Fresenius Kabi USA, LLC received FDA approval for its product, BORTEZOMIB for injection.¹ As a committed partner, Takeda Oncology welcomes a different formulation of bortezomib for patients who need access to additional options.

Given this recent approval, below are considerations for your practice on Medicare billing and coding for VELCADE[®] (injection, bortezomib, 0.1 mg) and the other bortezomib product:

- For VELCADE, providers should continue to use existing HCPCS code J9041. BORTEZOMIB for injection (Fresenius Kabi) has not been rated as therapeutically equivalent to VELCADE. Using HCPCS code J9041 to bill for BORTEZOMIB for injection on a Medicare claim may be contrary to the Average Sales Price (ASP) payment statute and the Center for Medicare and Medicaid Services (CMS) guidance². This could lead to an inappropriate level of reimbursement.
- BORTEZOMIB for injection's New Drug Application (NDA) was approved under the 505(b)(2) pathway. As such it should be considered a single source drug for Medicare billing and payment purposes. Based on CMS payment and coding guidance, claims for both BORTEZOMIB for injection and VELCADE should receive separate and distinct reimbursement based upon their unique average selling prices. Each product should be billed under its own HCPCS code.
- CMS typically requires new products like BORTEZOMIB for injection use a miscellaneous HCPCS code, such as J9999 (not otherwise classified, antineoplastic drugs), until a unique HCPCS code is assigned.³ Coverage policies and payment rates for BORTEZOMIB for injection also may not be established.
- VELCADE continues to have broad coverage across commercial and government health plans.

¹ https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/205004Orig1s000TAltr.pdf

² If a product was approved after October 1, 2003 under a unique FDA approval number or is not therapeutically equivalent to another product, its ASP based payment rate must be determined solely using its own ASP information. In such circumstances, CMS assigns a unique HCPCS code to the product to facilitate appropriate payment based on the pricing information for products produced or distributed under the applicable FDA approval. CMS, 5/18/07 – Update to Information Regarding Medicare Payment and Coding for Drugs and Biologics, available at http://cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_announcement.pdf/.

³ <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCSLevelIIICodingProcedures7-2011.pdf>

The considerations provided are for informational purposes only. We recommend that you consult your internal coding compliance and legal counsel to confirm specific coding, coverage and reimbursement guidelines. This document is not an affirmative instruction as to which codes and modifiers to use for a particular service, supply, procedure or treatment and does not constitute advice regarding coding, coverage, or payment for Takeda products. The information provided herein is without any other warranty or guarantee of any kind, expressed or implied, as to completeness, accuracy, or otherwise.

Patient Support

In support of patients prescribed VELCADE® (bortezomib), we continue to provide a robust suite of patient support services through our VELCADE Reimbursement Assistance Program (VRAP), which can help patients navigate the coverage and reimbursement process. Through VRAP, we can support patients and providers with insurance verification and prior authorization assistance, screen and enroll eligible patients into the VELCADE Patient Assistance Program, and provide information about alternative support programs.

If you have further, specific questions about coding and reimbursement for VELCADE, please call the VELCADE Reimbursement Assistance Program (VRAP) at 1-866-VELCADE (835-2233), Option 2.

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